DETAILED ACTION

Response to Amendment and Argument

1. Claims 1, 2, 4 and 6-54 are pending.

Claims 3 and 5 have cancelled.

Claims 6-54, drawn to non-elected inventions is withdrawn from examination.

Claim 1 has been amended.

Claim 54 has been added and is a non-elected invention. This claim reads on treating comprising administering an anti-androgen receptor inhibitor, which requires distinct and different method steps and method endpoint.

Claims 1, 2 and 4 are examined on the merits to the extent an antibody is used to detect the androgen receptor.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. The Examiner has reviewed the application and provisional applications in which Applicants believe they derive benefit. Applicants' claims under examination encompass a method of screening a subject for an increased risk or presence of breast cancer comprising obtaining both a breast tissue sample from said subject and a normal breast tissue to be used as a control. However, the specification, nor the two prior applications, PCT/US04/41631, filed December 13, 2004 and provisional application, 60/529,011 filed

December 12, 2003 seem to support this claimed method. Consequently, Applicants' are afforded the filing date of the instant application, May 31, 2007. Applicants are invited to provide evidence substantiating the claimed method in its entirety in the applications.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

4. The rejection of claims 1, 2 and 4 under 35 U.S.C. 102(e) as being anticipated by Thompson/ U.S. Patent number 7,029,859 B2 (filed March 5, 2001) is withdrawn in light of Applicants' amendment to claim 1 and corresponding arguments presented on page 7 of the Remarks submitted March 28, 2011. Claims 3 and 5 have been cancelled.

5. The rejection of claims 1, 2 and 4 under 35 U.S.C. 102(b) as being anticipated by Fujimoto et al. (Laboratory Investigation 80(9): 1465-1471, September 2000) is withdrawn in light of Applicants' amendment to claim 1 and corresponding arguments presented in the bridging paragraph of pages 7 and 8 of the Remarks submitted March 28, 2011. Claim 5 has been cancelled.

6. The rejection of claims 1, 2 and 4 under 35 U.S.C. 102(a) as being anticipated by Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003) is withdrawn in light of Applicants' presentation of new claim amendment and corresponding effective filing date.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***THIS IS A NEW MATTER REJECTION.***

Applicant has amended claim 1 to read,

"(Currently Amended) A method of screening a subject for an increased risk of or presence of breast cancer comprising: a) obtaining a breast tissue sample from the subject, and b) assaying ~~for the presence~~ the level of androgen receptor in the breast tissue sample, wherein ~~the presence~~ of an increase in the level of androgen receptor as compared to the level of androgen receptor in normal breast tissue indicates an increased risk of or presence of breast cancer in the subject., and c) identifying the subject as having an ~~increased risk of breast cancer when the presence of androgen receptor is identified.~~ "

Applicants state "[s]upport for these amendments can be found in the claims as filed, in paragraphs 82 and 89 of the specification, and elsewhere throughout the specification", see Remarks, 1st paragraph. However, these sections of the specification and seemingly the rest of the specification do not support *comparing* the level of androgen receptor in a breast tissue sample and normal breast tissue. Applicant should specifically point out where in the specification by page, line or section number, this comparison is contemplated or Applicant should delete the new matter.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Applicant's newly amended claim 1 reads on assaying the level of androgen receptor in breast tissue samples, however the claim does not include method steps as to how this is implemented, i.e. implementing an antibody. Furthermore, the term "level" usually corresponds to an amount, however that is not of record in the claims. Hence, the metes and bounds cannot be determined.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Moinfar et al. (Cancer 98(4): 703-711, August 15, 2003). Moinfar discloses immunohistochemical assays for AR in samples of breast carcinomas with antibodies, see page 704, Materials and Methods section. Moinfar notes AR was observed in normal epithelial cells "...(average proportion of stained nuclei, 40%; range, 10-70%). [Myoepithelial cells] were completely

negative for AR in most cancers (180 of 2000 [90%]). In some cases (10%), a small proportion of ME nuclei (1%) exhibited AR-positivity", see bridging paragraph of columns 1 and 2 on page 705. "[Moinfar] observed the presence of AR in 132 of 200 (66%) invasive and noninvasive breast carcinomas.", see bridging sentence of pages 709 and 710. It is clear the level of AR in the breast tissue samples was increased as compared to the normal breast tissue level. This observation reads on the method endpoint, indicative of an increased risk or presence of breast cancer.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a ***flexible schedule***, however she can normally be reached Monday through Friday, 8 am to 8 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Misook Yu, Ph.D. can be reached on (571) 272-0839. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
08 June 2011

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643